



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/837,042	04/11/97	SEMPLE	G 57714

HM11/0428
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EXAMINER
DELACROIX MUIRHE, C

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/28/98

Please find below and/or attached an Office communication concerning this application or proceeding. _____

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/837,042

Applicant(s)
SEMPLE et al.

Examiner
Cybille Delacroix-Muirheid

Group Art Unit
1654



☒ Responsive to communication(s) filed on Feb 6, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-11 and 13-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1-11, 13-18, 20, and 21 is/are allowed.

☒ Claim(s) 19 and 22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 19 and new claim 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivier et al., 5,506,207 in view of Hoeger et al. 5,296,468.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received Feb. 6, 1998.

Claim 12 is cancelled. Claims 21-22 are added. Claims 1-11 and 13-22 are currently pending.

The previous objection of claims 1 and 19, set forth in paragraph 1 of the office action mailed Oct. 2, 1997 is **withdrawn** in view of Applicant's amendment.

The previous rejection under 35 USC 112, paragraph 2, set forth in paragraph 2 of the office action mailed Oct. 2, 1997 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection under 35 USC 103 (§ 5 of the office action mailed Oct. 2, 1997) as it applies to claims 1-11, 13-18 and 21 are **withdrawn** in view of Applicant's amendment and the remarks contained therein. The previous 35 USC 103 rejection in paragraph 6 of the office action mailed Oct. 2, 1997 is **withdrawn** in view of Applicant's amendment and the remarks contained therein. However, said rejection in paragraph 5 still applies to claims 19 and 22. Applicant's arguments traversing said rejection have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Oct. 2, 1997 with the following additional comment:

It is Applicant's position that claim 19 is free from the prior art because the prior art, particularly to Hoeger, fails to disclose Applicant's claimed peptides, wherein the amf and aph

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residues at positions 5 and 6 are substituted with a carbamoyl or an alkyl carbamoyl. Applicant argues that Hoeger contains a broad disclosure of possible modifications to the peptide antagonists with the only "relevant" teaching being found in Example XIV where the lysine at position 6 is modified with naphthyl isocyanate. Furthermore, Applicant argues that the peptides of claim 19 have long duration of action in suppressing LH. Applicant contends that the Examiner's rejection of the claims by selecting from the obscure disclosure in Hoeger is based hindsight. There is no motivation or reasonable expectation of success to modify the peptides using the teachings of the Hoeger reference as suggested by the Examiner.

Said arguments have been considered but are not found to be persuasive.

It is the Examiner's position that the prior art provides sufficient motivation and reasonable expectation of success to arrive at the claimed invention. Rivier et al. teach Applicant's claimed GNRH antagonists and pharmaceutical compositions thereof. Specifically, the peptides at position 5 and 6 contain Aph which may be substituted with an acyl group, i.e. formyl or atz (3-amino 1,2,4 triazole). Please refer to col. 5, lines 10-40 ; col. 7, lines 20-30; col. 18, line 66 to col. 19 line 30; claim 15. Concerning the Hoeger patent, the arguments concerning Example XIV are well noted; however, it is the Examiner's position that the most relevant teachings are found in col. 3, lines 3-45, where Hoeger discloses that the Aph residue at positions 5 and 6 may be substituted with C(O)NHR₂, wherein R₂= H or alkyl. The disclosure in the Hoeger patent may be broad, yet the Examiner maintains that there is reasonable suggestion to motivate one of ordinary skill in the art to "try" the modifications suggested by Hoeger since Hoeger gives "no indication as to which parameters are critical or direction as to which of many possible choices is likely to be successful". Please see Merck & Co. V. Biocraft Laboratories Inc., 10 USPQ 2d 1843. Hoeger merely indicates that the preferred peptide in Ex XIV is effective to prevent ovulation at

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low dosages but does not specifically elaborate on the duration of action of the peptide.

Furthermore, it is held that a broad disclosure of modifications does not render any particular modification less obvious especially in view of the fact that the claimed composition is used for the identical purpose as the prior art. See Merck & Co. V. Biocraft Laboratories Inc., 10 USPQ 2d 1846. Both Applicant and the prior art teach GNRH antagonists. The Examiner maintains that both Rivier and Hoeger raise expectation of success and provide motivation by disclosing that the GNRH antagonist have high biopotency and are long-acting. Please see Rivier, col. 3, lines 25-28 and Hoeger, col. 8, lines 45-48.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Hence, claims 19 and 22 stand rejected.

Claims 1-11, 13-18, 20 and 21 are free from the prior art.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

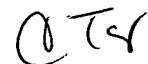
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM 

April 25, 1998


CECILIA I. TSANG
SUPERVISOR OF EXAMINERS
63027 1839